

# EXHIBIT A

In re 3M Bair Hugger

Expert Report  
John Abraham, Ph.D.

**I. QUALIFICATIONS**

I am currently employed at the University of St. Thomas. I am a professor of thermal sciences at the University of St. Thomas, a position I have held since 2002. I teach, carry out research, publish, and consult in the areas of heat transfer and fluid flow. Among my specialties are heat transfer involving the human body, heating blankets used during surgeries, air flow, laminar flow, turbulent flow, ventilation, and buoyancy (flow caused by heating). A copy of my current *curriculum vitae*, which contains a list of all cases in which I've given testimony in the past four years and my publications, is attached as **Exhibit A**.

My qualifications to render an opinion in this case include my education and training in heat transfer. My Ph.D is in thermal sciences and was completed in 2002 at the University of Minnesota. I have extensive experience in both airflow experiments and airflow calculations (commonly called computational fluid dynamics or "CFD"). I have published approximately 150 journal papers, given approximately 120 presentations, and written multiple books and book chapters, edited multiple books, and authored patents. I have worked as a consultant for multiple companies, particularly in the medical field. In addition, I have worked on the design and analysis of thermal blankets for patient warming.

**II. DISCLOSURES**

I have been asked on behalf of 3M to provide an independent evaluation of the Bair Hugger patient warming system and to determine whether or not the use of the Bair Hugger during surgery disrupts the air flow operating rooms. My opinions are based upon and are supported by both numerical calculations, experiments conducted in an actual operating room which validated my CFD model, and the literature and references cited in this report. I have considered additional documents, scientific and medical literature, and videos associated with Dr. Scott Augustine and his company, which are listed in **Exhibit B**. I reserve the right to supplement this report upon receiving of any additional material in connection with this matter and in particular upon receipt of additional material from Plaintiffs' experts, including especially computational files from Plaintiffs' CFD expert, Dr. Said Elghobashi.

I am being compensated \$250 per hour for review of records and preparation time in this matter and will be compensated \$500 per hour for deposition. I will not be compensated for trial appearances. My opinions as set forth in this report are stated to a reasonable degree of scientific certainty and I will testify to them if called as a witness at trial or deposition.

### III. OPINIONS

#### Summary of Opinions

My opinion, as an expert in heat transfer and air flow, is that forced-air patient warming does not meaningfully impact air flow currents in operating rooms and does not increase the risk that airborne bacteria and bacteria-carrying particles will reach the surgical site during a procedure. My opinion is supported by my own calculations, and by an air flow visualization experiment carried out in an actual operating room. The contrary view is unsupported by the facts and relies upon poorly performed and described research completed at the direction of a business competitor.

The Bair Hugger is in a class of devices commonly referred to as forced-air warming devices. The purpose of these devices is to maintain patient healthy body temperature by blowing a gentle flow of warm air on their skin. The warm air heats the patient, prevents hypothermia, and improves patient outcomes. The effectiveness of these devices is strongly established in the scientific literature and is generally accepted by medical professionals.

I have reviewed the written reports from the plaintiff's experts. In particular, I have carefully reviewed the report submitted by Dr. Said Elghobashi. Dr. Elghobashi has performed a numerical simulation of air flow within a room with and without a forced-convection warming system. His conclusions are based on work which has multiple serious errors, each of which will be discussed. Furthermore, his work does not adhere to scientific standards and methods which are accepted within the thermal science community. In addition, his work in this case contradicts the methodology he has employed in his own previous work.

By way of summary, my opinions are:

- The Bair Hugger warming system does not interrupt or disrupt downward clean airflow from washing over the patient and the surgical site.
- The above conclusion is based on my own calculations and experiments.
- The consensus of scientific literature supports my conclusions.
- The Plaintiff's fluid flow expert's report is flawed in multiple respects which make his conclusions invalid.
- Online videos of operating room airflow created by Dr. Scott Augustine and his employees are misleading and unreliable.

The following will discuss the underlying basis for these conclusions.

#### **A. THE PATTERN AND DISTRIBUTION OF AIR IN A GIVEN ROOM CAN BE ACCURATELY PREDICTED BY USING BASIC LAWS OF PHYSICS AND A HIGH-SPEED COMPUTER**

##### **1. Description of Computational Fluid Dynamics**

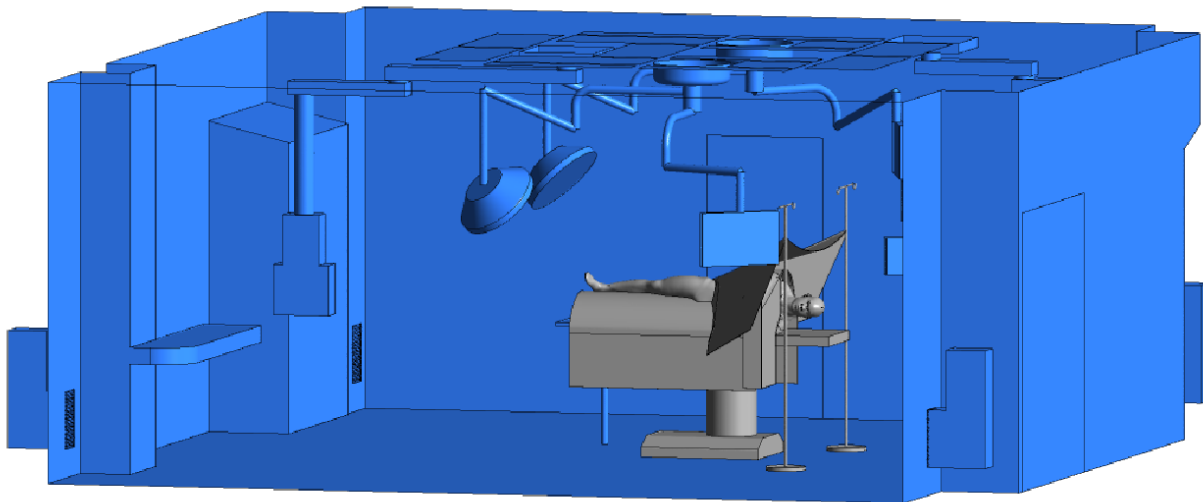
The technique of computational fluid dynamics ("CFD") is a mature science that has been developed over many decades. It is based on fundamental physics of conservation of mass, conservation of momentum, and conservation of energy. These physics equations are solved at a

multitude of locations (called grid cells) which are distributed throughout the fluid space. The “fluid space” referred to here is the air space (air is a fluid).

***Step 1 of the analysis - geometry***

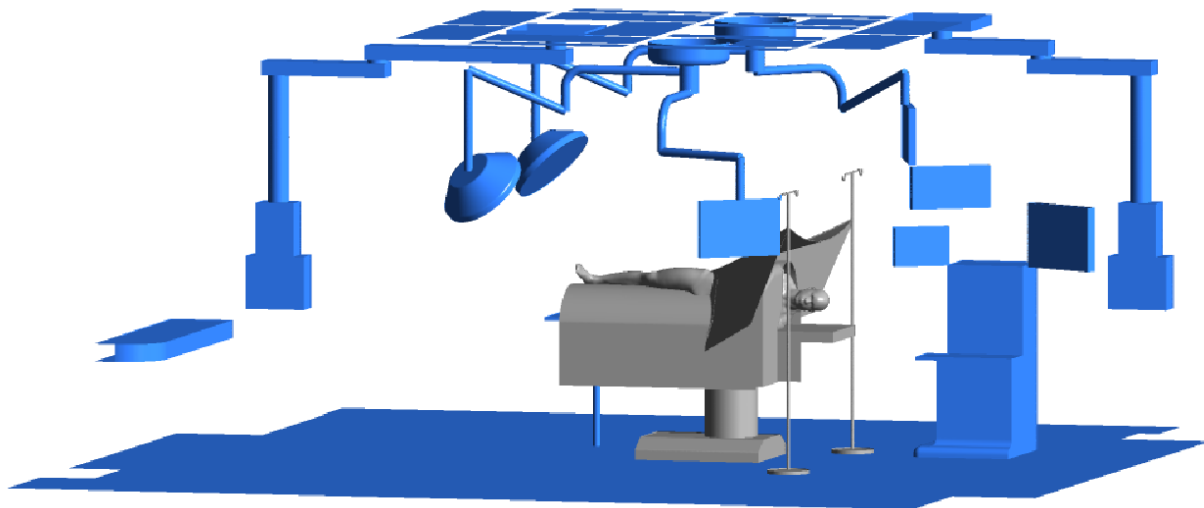
The first step in a numerical simulation is to create a computerized rendition of the fluid region. Figure 1 shows a rendition of the operating room under consideration in this calculation.<sup>1</sup> It has dimensions taken from an operating room that was used in the experiments described later. The figure shows key features of the operating room including a patient, surgical drape, a table, and various obstructions such as surgical lights. The actual measurements of these items were used to model the operating room for my CFD model. In addition, the computerized model includes inlets and outlets where the air enters and leaves the room. In this case, the inlets are confined to the ceiling and coincide with the downward air flow vents. The exit vents are positioned on the walls.

**Figures 1a and 1b are presented;** the first figure shows the operating theater including the side walls, ceiling, and floor. The second part is a replica of the first with the exception of walls and ceiling that are hidden for ease of viewing.



**Figure 1 (a) – Computerized image of the operating room including the walls.**

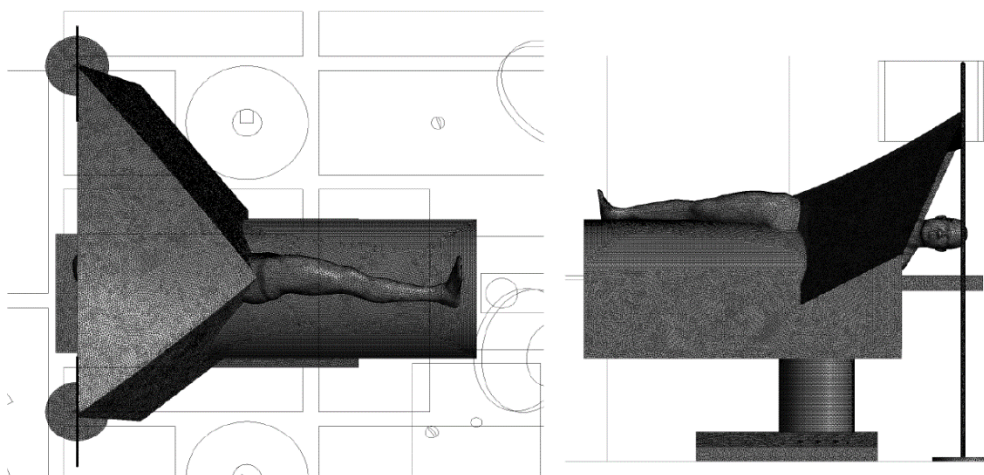
<sup>1</sup> This is a computer assisted rendition of a real operating room in Edina, Minnesota. What is shown is based on actual measurements of what is shown here. The experiment described later took place in this operating room.



**Figure 1 (a) – Computerized image of the operating room with walls hidden**

***Step 2 of the analysis – calculation of cells***

The next step in the analysis is to subdivide air space into the multitude of grid cells. This subdivision step determines the accuracy of the final calculations. Larger numbers of grid cells result in a more accurate solution. In the calculations that are presented here, up to 60,000,000 grid cells were employed and high accuracy was obtained. Figure 2 has been prepared to give a perspective on the number of grid cells. Grid cells along some of the surfaces in the operating theater are shown in two different views. At each grid cell, physics equations were solved to obtain flow patterns. Grid cells completely filled the air space which occupied the entire operating room.



**Figure 2 – Images of the cells projected onto the surgical surfaces**

***Step 3 of the analysis - equations***

The next step is the solution of fluid flow equations (conservation of mass, momentum, and energy) at each grid cell location.

The model used here is the Large-Eddy Simulation method (LES) which is the preferred way to calculate flows of this nature, that are unsteady, with buoyancy, and potential eddies [1-3]. This is the appropriate modeling choice for flows that may have eddies/vortices, unstable plumes, cyclonic motion, and mixing.

It is important in this model to account for buoyancy effects (hot air rises) because the Bair Hugger releases warm air which rapidly mixes in with the operating room air, also known as ambient air. To accomplish this, a buoyancy model must be included described in [4]. Here, the well-established Boussinesq approach was used. The influence of buoyancy on turbulence was also included.

#### ***Step 4 of the analysis – conditions***

Next, the solution requires knowledge of the flowrate and temperatures of the air flow at the inlets. Air flow can be expressed in velocity, volumetric flow, or mass flowrate. Temperature is typically expressed in degrees Celsius or degrees Fahrenheit. In the calculations performed here, flowrates (air velocity) were measured for both the Bair Hugger system and for the downward air-flow in the room.

The boundary conditions consisted of inlet conditions at the ceiling which were a uniformly applied downward volumetric flowrate of  $1.1 \text{ m}^3/\text{s}$  ( $39 \text{ ft}^3/\text{sec}$ ) with an inlet temperature of  $59^\circ\text{F}$  ( $15^\circ\text{C}$ ). The volume of the room is  $5190 \text{ ft}^3$  ( $147 \text{ m}^3$ ) so that the ventilation flow resulted in one air change every 130 seconds. The corresponding mass flowrate is  $1.39 \text{ kg/sec}$  ( $3.06 \text{ lb/sec}$ ). The warm air from the Bair Hugger blanket was treated as a second inlet to the room near the patient's head and the temperature of the air leaving the blower and entering the blanket was set to the highest value of  $43^\circ\text{C}$  ( $109^\circ\text{F}$ ). This assumes a worst-case scenario; the temperature of the air exiting near the patient's head should be significantly less than  $43^\circ\text{C}$  ( $109^\circ\text{F}$ ) – the value used in these calculations was  $43^\circ\text{C}$  ( $106^\circ\text{F}$ ). I have reviewed temperature measurements by Dr. Thomas Kuehn showing an air temperature of  $24^\circ\text{C}$  ( $75^\circ\text{F}$ ) approximately 6 inches from the patient's head.

Measurements were made using a Bair Hugger Blower model 750 and an Upper Body Blanket Model 522 to determine the flowrate through the system. The experiments found a flowrate of  $0.023 \text{ kg/sec}$  for a partially obstructed blanket and  $0.025 \text{ kg/s}$  for a fully open blanket.

#### ***Step 5 of the analysis – validated method***

The first step in validating the CFD method is to test the numerical methodology against known experimental results. It is important that the computer model be validated against a close representation of the calculated scenario. Dimensions measured from the room were utilized to validate this study. Insofar as the method used here is similar to that employed in validated studies, its numerical methodology is validated; details of the employed numerical methodology are available in [5-7].

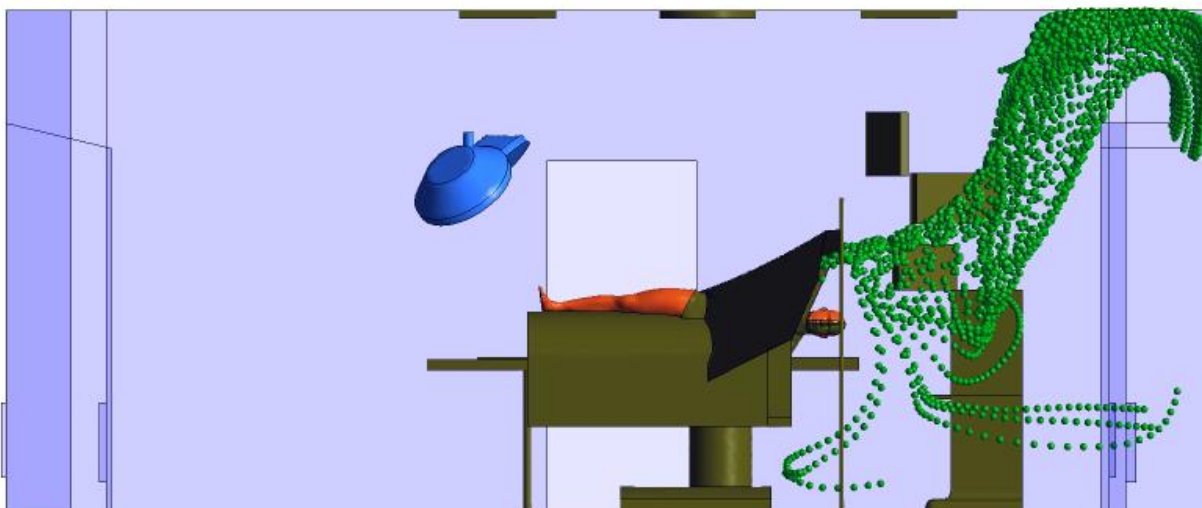
The results from the calculations are compared with measurements made in the operating-room experiment. From the calculations, the room-averaged temperature was  $62^\circ\text{F}$  for an 8.1 million grid-cell calculation. The measurements of the room were  $61^\circ\text{F}$  during the procedure. This is

near perfect agreement. The temperature calculated three inches above the floor was 60 °F and the measurements were 60.5 °F, again near perfect agreement. The temperature at the edge of the bed was measured to be approximately 61 °F while the measurements at the same location were 60.3 °F. In addition, as will be discussed later airflow patterns from the calculations matched those of the experiments.

#### ***Step 6 of the analysis – determine results***

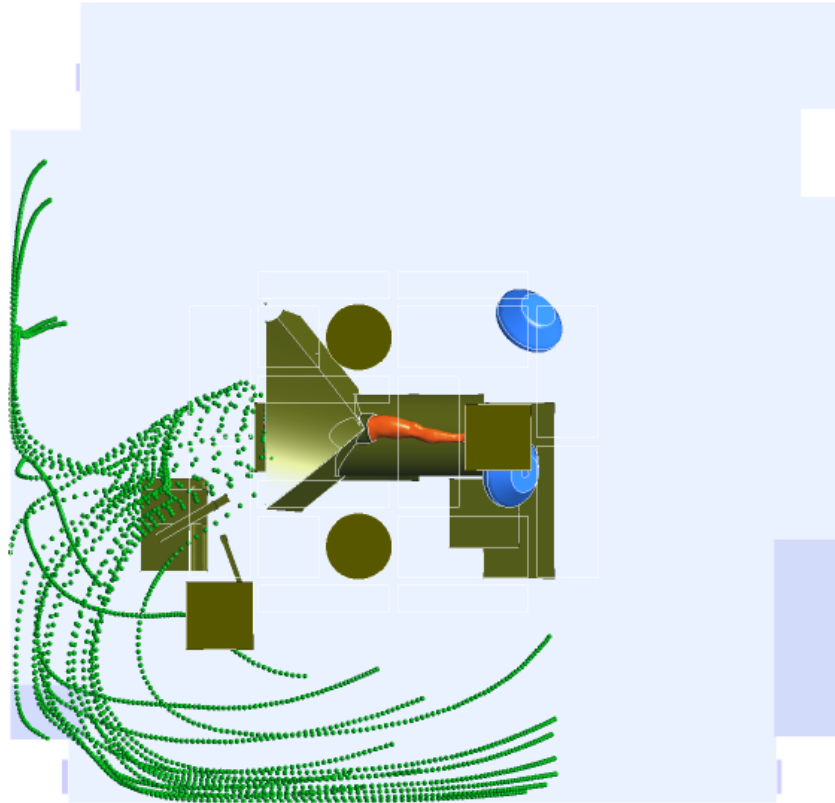
The CFD analysis outputs all fluid properties at all grid-cell locations. The results can be displayed as a grid of arrows which show the flow patterns, colored contours which represent temperature or velocity, streamlines which follow instantaneous airflow pathlines, or three-dimensional plumes. Some of these visualization techniques will be provided in this report. In the figures which follow, green dots or lines depict the air streamlines released by the Bair Hugger. Blue dots or lines represent the operating room air streamlines supplied by the several ceiling vents. Purple dots represent streamlines that emerge from beneath the table.

Figure 3 shows a side view of the air emerging from the patient warming device and traveling vertically upwards and away from the surgical area. The green spheres in the figure are along airflow streamlines. Areas of the room without green spheres are spaces free of Bair Hugger flow. The streams impact the side walls of the operating room far from the patient at the right side of the image. A top-down view of the streamline patterns is presented in Figure 4. There, it is seen that the flow emanating from the patient region does not encroach on the patient or the surgical area.



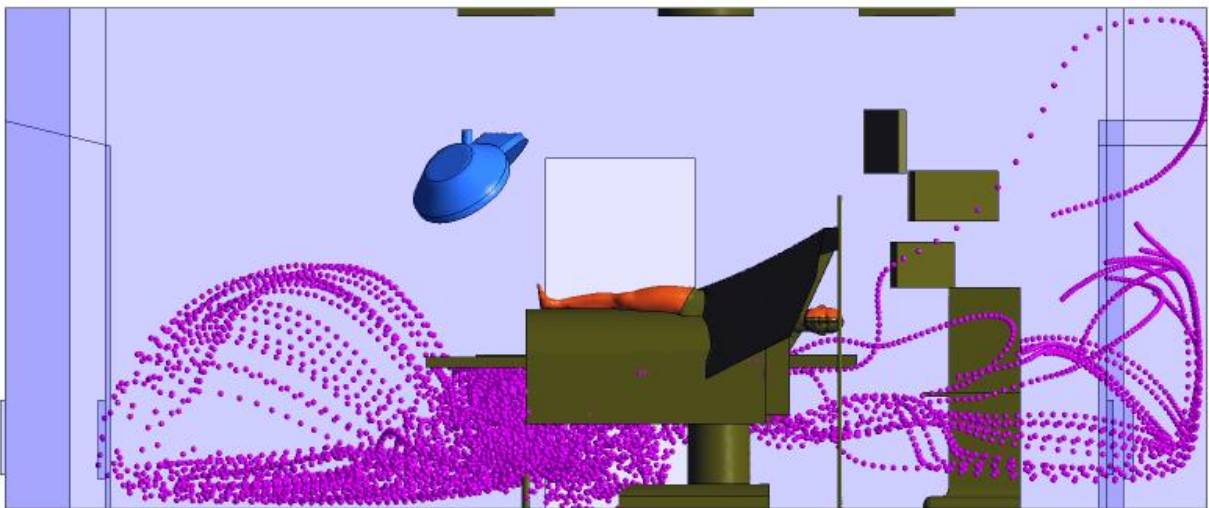
**Figure 3 – Side view of the simulation, airflow streamlines from Bair Hugger are shown in green, Bair Hugger set to 43 °C (109 °F), inlet airflow venting is 59 °F.**





**Figure 4 – Top view of the simulation streamlines from Bair Hugger, Bair Hugger set to 43 °C (109 °F), inlet airflow venting is 59 °F.**

Next, Figure 5 shows the patterns of streamlines released originating from underneath the operating table. It can be seen that any flow which leaves the table zone travels horizontally away from the table. The air neither sinks to the floor nor does it rise to invade the surgical zone. Any rising fluid occurs far from the operation zone. These results show that streams from beneath the table are not raised into the operation region.

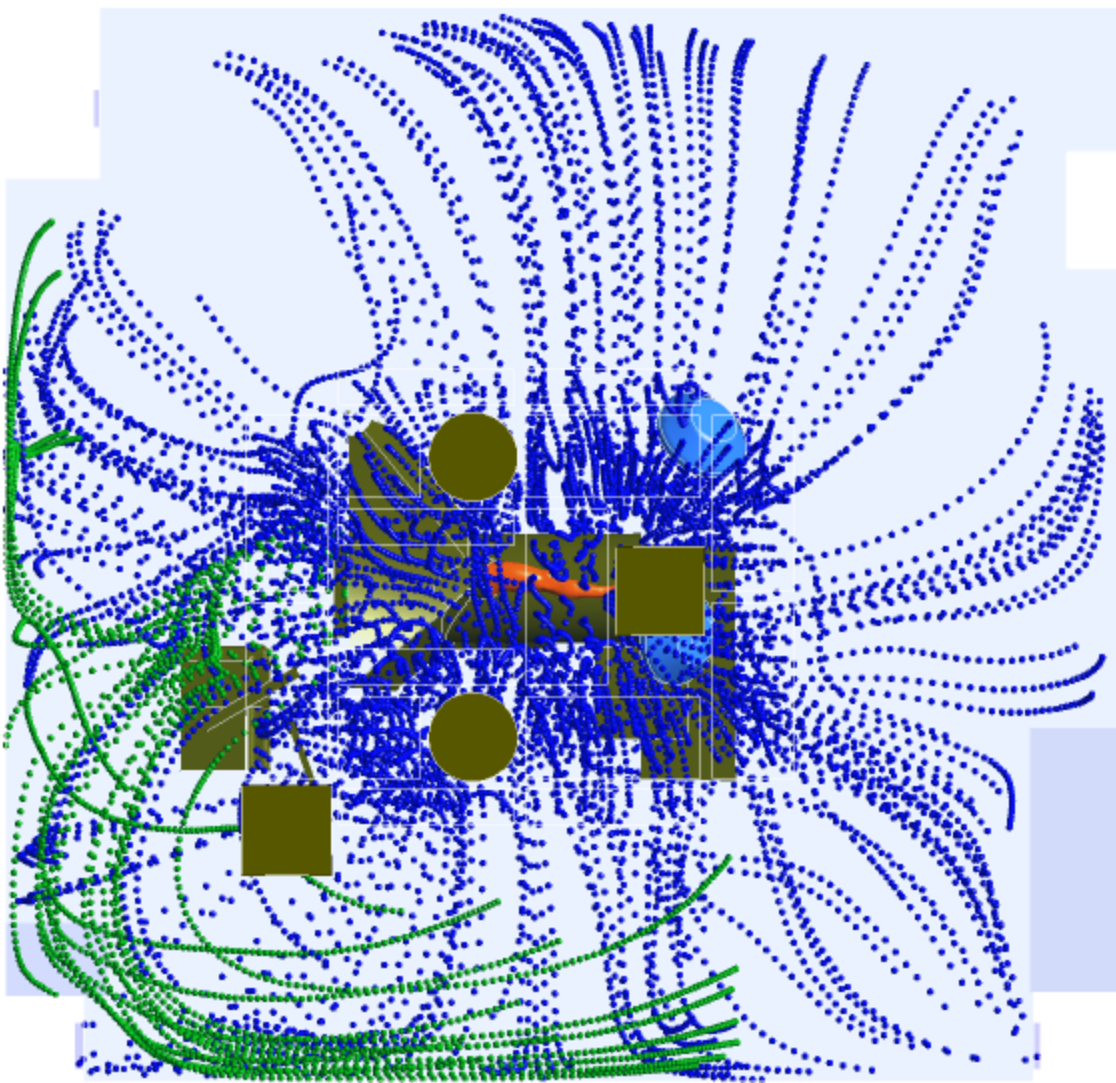


**Figure 5 – Side view of the streamlines from beneath table, Bair Hugger set to 43 °C (109**

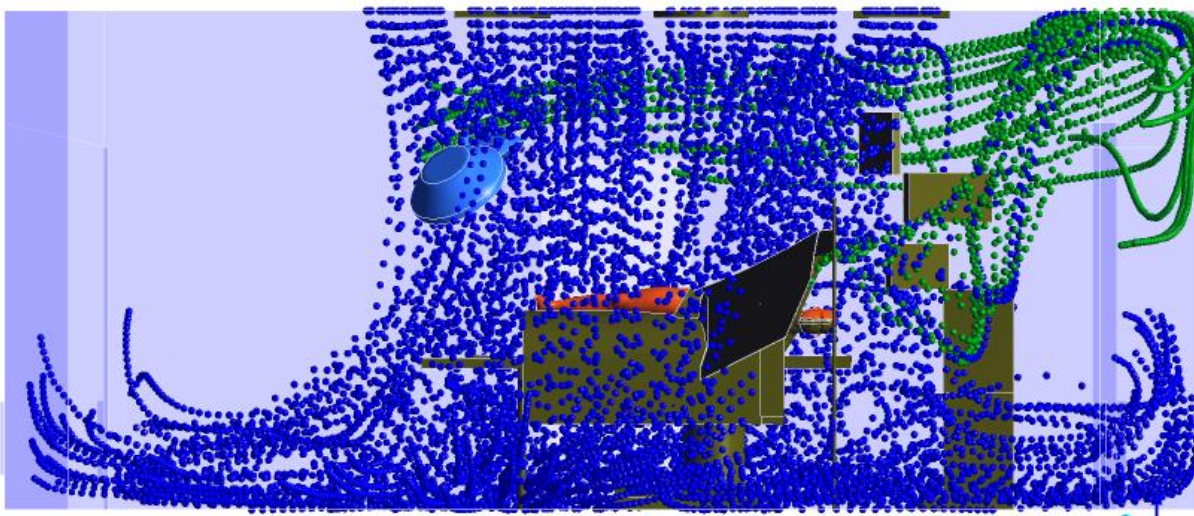


**°F), inlet airflow venting is 59 °F.**

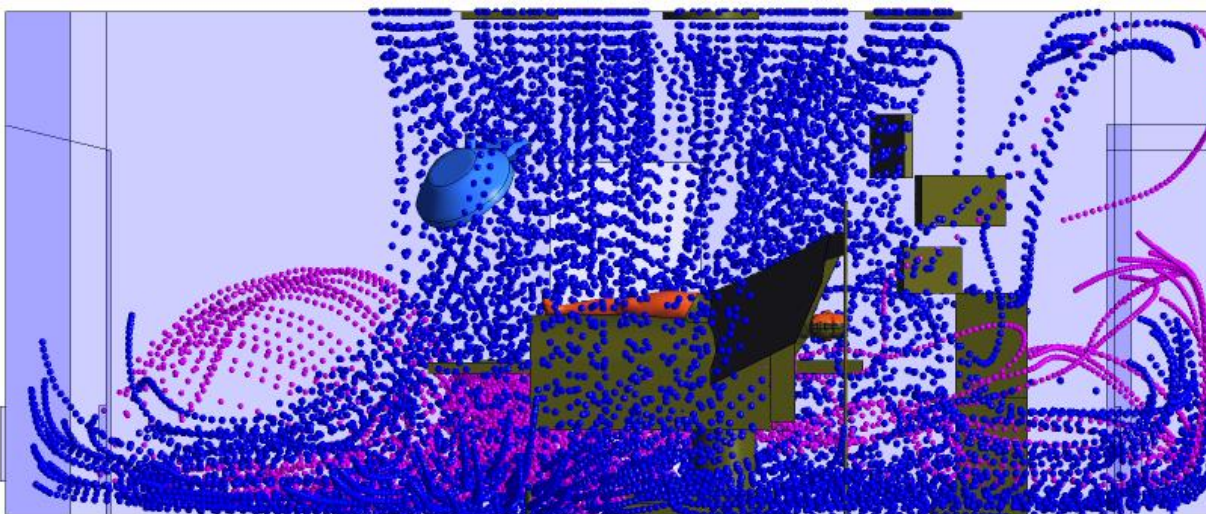
Accompanying figures show both downward air flow streams in blue and other streams in green and purple, respectively. These figures show that downward airflow venting above the surgical table washes over the patient, including the surgical site. In Figure 6, a view from above is given where the streamlines from the vents in the ceiling are colored in blue and the streamlines from the Bair Hugger are in green. Again, it is seen that only blue-colored air is contained above the surgical site. A complementary image is shown in Figure 7 as a side view. Again, it is seen that only blue-colored flow washes over the surgical site. A final calculation result is shown in Figure 8. There, purple colors signify streamlines from beneath the table and blue from the downward airflow vents. Again, only blue fluid enters the surgical region. These results show that any air from beneath the table does not rise above the table with the Bair Hugger on. The results also demonstrate that the air released from the Bair Hugger blanket is washed away from the surgical region and does not disrupt the downward airflow of the operating room.



**Figure 6 – Top view of streams from downward airflow vent (blue) and from Bair Hugger (green). Bair Hugger temperature 109 °F, downward airflow vent 59 °F.**



**Figure 7 – Side view of streams from downward airflow vent (blue) and from Bair Hugger (green). Bair Hugger temperature 109 °F, downward airflow vent 59 °F.**



**Figure 8 – Side view of streams from downward airflow streamlines vent (blue) and from beneath table (purple). Bair Hugger temperature 109 °F, downward airflow vent 59 °F.**

A summary of these findings from the various scenarios I ran through the computer model is that in no instance does air from beneath the table or from the Bair Hugger encroach on the surgical site. Images from figures 3-8 could be replicated at other time instances and the same conclusions would be drawn. These results are confirmed by validating air flow visualization experiments carried out in this same operating room.



## B. THE ACTUAL AIRFLOW IN THIS OPERATING ROOM WAS THE SAME AS PREDICTED IN THE CFD MODEL

To validate the calculations, real-life experiments were performed. The goal of the experiments was to show airflow patterns in an actual operating theater with a surgical team and a patient. During the experiments, airflow patterns were visualized through the injection of visible water vapor (a dense cloud) into the room. The water vapor was injected for two scenarios. In the first scenario the Bair Hugger was on, in the second scenario, the Bair Hugger was off. We found that the airflow patterns in the room were the same regardless of the Bair Hugger. In fact, the experiments included clouds injected directly at the surgical site, which were halted and turned away by the clean airflow in the room. In no case did airflow from beneath the table, from the exhaust of the Bair Hugger, or any other location outside the sterile field enter into the surgical site. These findings match those of the calculations which were described earlier in this report.

## C. THE AIR EMERGING FROM BLANKET SPREADS AND MIXES QUICKLY

The opposition, including Dr. Elghobashi, has claimed that Bair Hugger exhaust air travels from the blanket to the floor, picks up pathogens, and then lofts them back over the table and impinges them on the surgical site. This claim is contrasted by the experiments and calculations that I conducted. It also conflicts with basic physics. In order to maintain enough energy to accomplish this herculean task, the airflow must maintain a coherent jet. That is, the air must stay in a thin fast moving stream. But this is not what happens. To prove this, schlieren images were taken of air exiting the Bair Hugger blanket. The schlieren method is an optical measurement of fluid flow based on density differences. A schematic of the test facility is provided in Figure 9. Images from the schlieren imaging are provided in Figure 10.

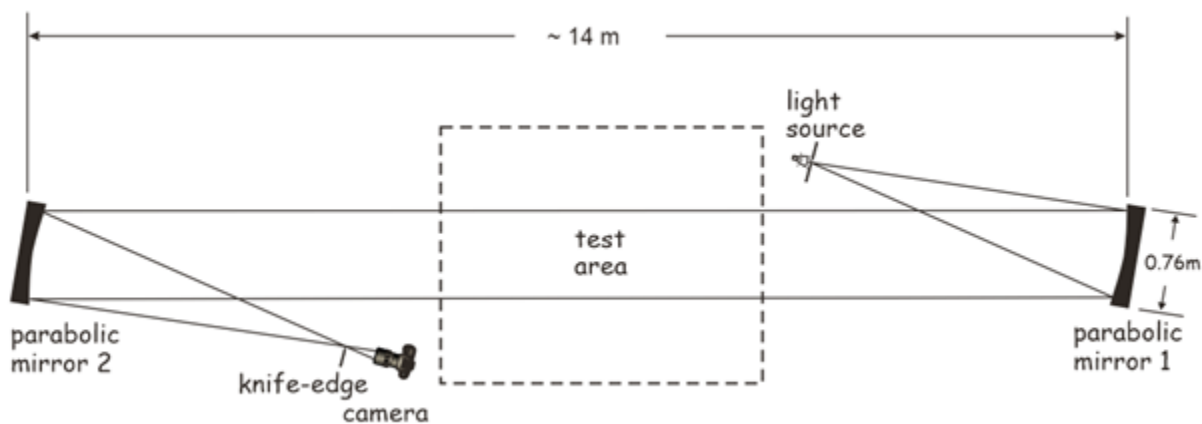
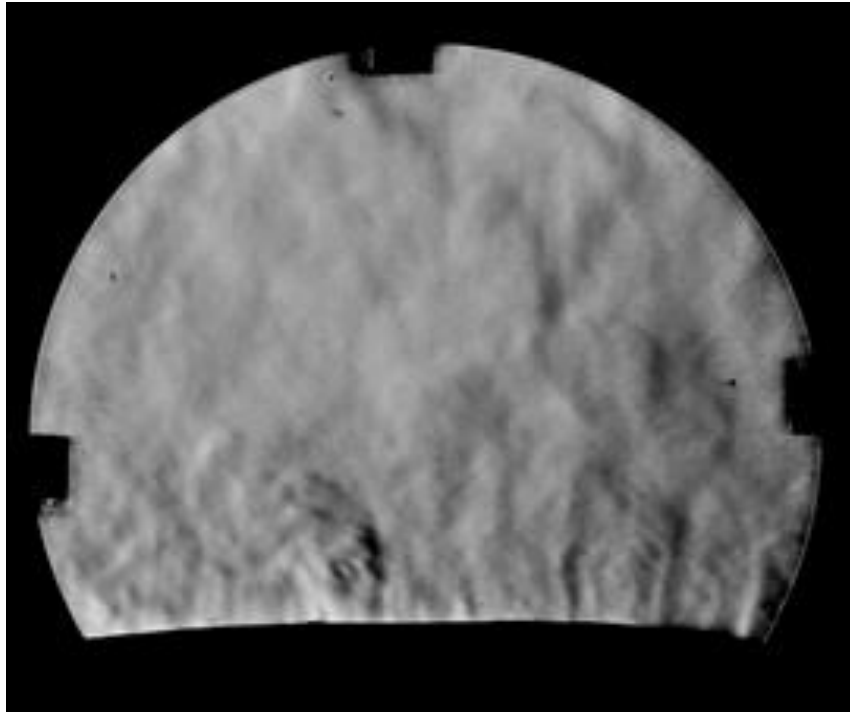


Figure 9 – Facility for schlieren experiments (image from Dr. Settles report).



**Figure 10 – schlieren photographs of jet spreading and mixing within a few cm of blanket microperforations (image from Dr. Settles report).**

What is shown confirms our own experience with buoyant flow: the air emerging from the Bair Hugger mixes rapidly into the room air and loses its jet characteristics quickly. Furthermore, the air emerging from the blanket will slowly rise, not sink to the floor. Consequently, it is not possible for warm air from Bair Hugger to travel to the floor, pick up pathogens, and then turn around and rise into the surgical field.

#### **D. THE BAIR HUGGER DOES NOT HEAT THE OPERATING ROOM**

The model shows that Bair Hugger forced-air warming does not add appreciably to the cooling load of the operating room. Figure 11 has been prepared to show temperatures along a plane passing through the operating room. The heated air from Bair Hugger is directed away from the surgical site, the room temperature is dominated by the air entering the room from the ceiling vents.



The use of warming technologies to maintain patient temperatures is an important part of surgical patient care [8-16]. Among the various technologies, forced air warming is a common approach that is easy to employ and efficacious. Recently there have been claims that forced-air warming systems can disrupt otherwise clean airflow in a laminar-flow environment. I have reviewed the claims and have formed an opinion. My opinion is that there is no compelling evidence that the use of forced-air warming systems such as the Bair Hugger meaningfully disrupt operating room airflow and therefore do not increase the risk of surgical site infection by that purported mechanism. Claims that the Bair Hugger exhaust air somehow travels down to the operating room floor, picks up bacteria, lofts them above the surgical table, and finally deposits them in the surgical zone are contradicted by both numerical simulation and by experimentation and by basic laws of physics.

In [17], a study was performed with simulated patients. Multiple forced-air-warming systems were used. Culture plates were placed on the abdomens of volunteers. The study failed to find an increase in contamination rates with forced air warming. The authors concluded that “convective warming therapy, when appropriately applied, does not increase the risk of airborne bacterial wound contamination in the operating room.”

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A later study [19] used multiple forced-air-warming systems and failed to find a significant rise in bacterial counts with the use of the devices. This study tested ultra-clean rooms that were empty, with a placed patient and staff prior to warming, and during warming. The study included sampling of air during the warm-up period and found no significant increase in pathogen counts with the forced-air warming on compared to off. The overall levels were below that required for a clean room.

In [20], experiments were completed with sampled air with a laminar system on and volunteers with psoriasis who had increased shedding of skin squames. They employed a forced-air warming system with different conditions ranging from empty to filled rooms. Air near the surgical site was sampled and there were no positive cultures. They also used a smoke device to visually assess airflow and found no disturbance by the device. They also found that even with psoriasis patients, cells are not transported from the skin to the surgical site. This study rebuts the claims in the present case. First, the laminar flow was not disturbed. Second, contaminated air from beneath the table was not carried by buoyant flow into the surgical site. Third, pathogens from the patient's skin were not carried to the surgical site. Their conclusion was, "No colonies were grown on any of the groups tested and our results suggest that the patient warming system does not influence bacterial counts at the operating site in an ultraclean air-ventilated theatre, even with patients who have high shedding of skin".

In [21] A Bair Hugger was studied with 16 patients who underwent abdominal vascular surgery in a standard, positive-pressure operating room. They showed that there is no increase in bacterial content around the patient and no wound infections occurred. They concluded that the warming system does not lead to increased bacterial contamination in the operating room and is unlikely to affect the surgical field.

In [22], a study of 30 patients was made, some received forced-air warming while others did not. Any increase in bacterial loading was much less than any worsening of air induced by surgical staff. In fact, bacterial counts were lower with the forced-air warming than they were in the operational environment without warming. They conclude that "the Bair Hugger system does not pose a real risk for nosocomial infections". They also monitored patients for 6 months after surgery and were able to rule out delayed infection.

A supporting study [23] using a volunteer patient and heated mannequin surgeons did not find any worsening of air quality with the use of forced air warming under laminar flow conditions. Tracer particles were used and a reduction of particle load was measured. The particles spanned the range of 0.5 – 1 micrometers and were released for six different locations. Flow patterns were assessed with smoke; the researchers found no significant impairment of laminar flow. It is noteworthy that the scientists also investigated the impact of heat and found that heated air from the Bair Hugger device had no impact on particle motion. The researchers also released smoke above the surgical site with the blowers operating. They found that "the presence of a forced-air warming system did not create an upward draft or interfere with normal and effective function of the laminar flow process." This finding contradicts the claims made in the online videos which are discussed later.

A 2013 society article [24] evaluated this issue in a review and found insufficient evidence to support changes to current practice. The authors filtered their literature review through a thorough set of inclusion criteria comprising eight parts.

The same year, a literature review [25] was performed which examined 192 information sources; 15 met the authors' inclusion criteria. Only three studies actually followed patients who were warmed by forced-air-warming devices. They concluded that clinical practitioners should continue to use and clean FAW systems according to manufacturers' instructions.

As part of a Doctor of Nursing Practice degree [26], another review was performed which found "insufficient evidence to suggest delayed or discontinued use of forced-air warming". The studies' lack of data showing patient surgical site contamination and inability to conclude that the forced air warming devices actually caused surgical site infections due to intraoperative contamination do not support a change to clinical practice."

In [27], the authors asked whether forced air warming blankets increase the risk of surgical infection. They recommended no change to current practice.

In 2015, [28], the clinical success of forced-air warmers was restated and the author reported that "we found no conclusive evidence that forced-air warmers increase the incidence of surgical site infections".

Taken together, these studies, combined with the analysis presented here, provide strong evidence that use of the Bair Hugger does not increase the risk of surgical site infections by moving contaminated air to the surgical site.

There have been contrary publications which suggest otherwise. These publications are very limited, use flawed techniques, and do not show or claim a causal link to infections. Moreover, they provide insufficient information from which to evaluate the claims. For instance, [29] involved cultures from a forced-air-warming system where bacteria were found. Pathogens were also found on other medical equipment. There is no evidence that bacteria ever emerged from the forced-air device or that emitted bacteria could make it to the surgical site.

A number of other papers appeared in the literature which were authored by employees of a competing patient-warming device company or supported by a competing company [30-36]. These articles typically did not give velocity, location, or direction of the flow tracers. Flow tracers that were unreasonably large were used, and the experimental set-up was not described. In particular the dimensions and locations of the components in the room, the presentation of the patient, the movement of the surgical staff, the flowrate of the blower, and other key variables were not provided. The flow tracer injection was a faulty design for monitoring the fluid particles in the surgical site. These papers do not meet the standard of a fluid mechanic or heat transfer journal. None of these papers showed pathogens released or emitted from a forced-air warming device that reached the surgical site. None of these papers showed pathogens which were carried by forced-air warming currents to a surgical site. None of these papers showed that any pathogens contained within the device are emitted in the exhaust air. These papers did not adequately characterize the status of the tested devices, did not assess the accuracy of the



particle-counting examination, and made unsubstantiated claims about particles generated within the device. Furthermore, the composition of the particles were never tested so their origination is not known. Finally, these studies do not adequately address the issue of how any potential contaminants, even if they emerged from the blower and were able to pass out of the blanket, would somehow be directed to the surgical site.

In [37] and [38], lab experiments and simulated surgeries were performed to test temperatures and air particle concentrations in a surgical environment. They found elevated fabric temperatures with forced-air warming. Minimal information was given in these experiments, in particular regarding the physical situation. Additionally, incomplete information was given with regard to the flow visualization. It is not possible to assess the quality of this work based on the reports. The papers were not published in a journal dealing with fluid mechanics or with heat transfer. Their flow visualization particles are too large, their temperature measurement technique was not fully described and their findings are unsubstantiated.

It is noteworthy that the authors of [37] and [38] incorrectly claim that the competing device is a radiant warming system. In fact, it warms primarily by conduction. The authors also claim that the Hot-Dog device creates a unidirectional heating. In fact this is a false claim. Among the missing information is the background concentration of particles in the room. The authors did not culture any of the particulates and they did not provide adequate temperature and flowrate information. They make unsubstantiated claims that “waste heat” causes airflow disruption. In addition, their injection of particulates is likely the cause of the observed airflow patterns. Finally, there is a logical inconsistency with respect to these results. On the one hand, they claim to observe a vortex of flow when a forced-air warming device is used. On the other hand, they claim that this vortex draws in particulates from underneath the table. It isn’t clear that this was actually observed; it appears to be a hypothetical and unsupported statement. In fact, it is difficult or impossible for a detached horizontal vortex to vertically move particles from outside the vortex to inside the vortex. The authors of this study do agree, however, that the forced-air warming devices do not exhaust contaminated air into the surgical area. In [38] for instance, they write “it does not appear that the forced-air-warming device itself blows potentially contaminated warm air directly into the Howarth enclosure”.

## **F. REBUTTAL TO PLAINTIFF’S FLUID DYNAMICS EXPERT**

The plaintiffs have submitted an expert report from fluid mechanician Dr. Said Elghobashi. Dr. Elghobashi concludes that the operating room flow is disrupted by the Bair Hugger, and that the Bair Hugger mobilizes theoretical squame particles and delivers them to the surgical site. Dr. Elghobashi’s conclusions are based on flawed assumptions and faulty analysis, and reflect a methodology which is not accepted within the fluid mechanics community.

Dr. Elghobashi’s errors include the following:

1. He performed no experiment to validate his model, and so his conclusions are unconfirmed and unreliable.
2. He does not clearly define how the Bair Hugger heated air enters the room. From the incomplete description given, it appears that he has made a serious error by allowing the heated air to emerge along a slot at the bottom edge of the drape. This assumption is in

stark contrast to what occurs in the actual use of the Bair Hugger device, where heat from the blanket emanates primarily from the head and neck of the patient. Dr. Elghobashi's incorrect assumption invalidates his analysis.

3. He has removed the most significant heat source—the surgical lights—from his analysis, despite defining it as part of his model.
4. He claims to present information along two precisely located planes that pass through the modeled room but in fact his results do not correspond to his purported location.
5. His modeling of skin cells as spheres not only has a mathematical error but is based on a faulty premise.
6. He incorrectly treats collisions as perfectly elastic (they are not) and then contradicts himself later.
7. His inlet vent conditions have two serious errors related to the incorrect duct assumptions and to the neglect of exit vanes.

I will discuss each of these issues in detail.

### **F.1. Dr. Elghobashi has not validated his calculations.**

All computational results must be validated. Without validation, there can be no confidence in the results. Typically, validation is a procedure wherein calculated results are compared with experimental values. The experimental results should be obtained from experiments that match the essential details of the calculation.

The importance of validation is well known in the field of fluid mechanics. For instance, NASA, [39] discusses the importance of validating modeling calculations. NASA describes validation as follows:

*“[Validation is] the process of determining the degree to which a model is an accurate representation of the real world from the perspective of the intended uses of the model. (AIAA G-077-1998)*

*Validation has also been described as "solving the right equations". It is not possible to validate the entire CFD code. One can only validate the code for a specific range of applications for which there is experimental data. Thus one validates a model or simulation. Applying the code to flows beyond the region of validity is termed prediction.*

*Validation examines if the conceptual models, computational models as implemented into the CFD code, and computational simulation agree with real world observations. The strategy is to identify and quantify error and uncertainty through comparison of simulation results with experimental data. The experiment data sets themselves will contain bias errors and random errors which must be properly quantified and documented as part of the data set. The accuracy required in the validation activities is dependent on the application, and so, the validation should be flexible to allow various levels of accuracy.*

*The approach to Validation Assessment is to perform a systematic comparison of CFD simulation results to experimental data from a set [of] increasingly complex cases.”*

These views are reflected by experts in the field such as [40] who write:

*“Verification and validation really is an essential process that every CFD user needs to keep in mind. We have all encountered situations where computers have fallen victim to GIGO (Garbage In-Garbage Out) and happily spew out reams of useless data.” Any production Navier-Stokes solver is a complex piece of software that is just as susceptible to this as anything else. So if you or your business are going to invest the time, energy, and money to conduct a CFD analysis, how can you be sure that the results are valid?”*

In the peer-reviewed scientific literature this is also well known. For instance, [41] write

*“Verification and validation (V&V) are the primary means to assess accuracy and reliability in computational simulations.”*

Scientific organizations such as the American Institute of Aeronautics and Astronautics (AIAA) and the American Society of Mechanical Engineering (ASME) also recommend experimental validation of computer models (AIAA, 1998 [42]).

Dr. Elghobashi understands the process of comparing computational results to experiments. For instance, in 2014 he reported on numerical and experimental studies of flow in a human body (Wang et al., 2014 [43]). Dr. Elghobashi was Chair on a PhD wherein validation of CFD code was an entire chapter. There, the CFD calculations were validated against exact analytical solutions (Rosso, PhD Thesis, 2016, [44]).

He has previously compared computations with experiments in prior works such as (Kim et al., 1993; Elghobashi and Lasheras 1996; and Cleckler et al., 2012 [45-47] as examples. In summary, Dr. Elghobashi did not validate his numerical model against experiments that matched the computational results, even though validation is understood within the scientific community as being an essential component to problems of this nature.

**F.2. The expert does not clearly define how the Bair Hugger heated air enters the room. From the incomplete description given, it appears that he has made a serious error by allowing the heated air to emerge along a slot at the edge of the drape. This assumption is in stark contrast to what happens during actual use of the Bair Hugger device and invalidates his analysis.**

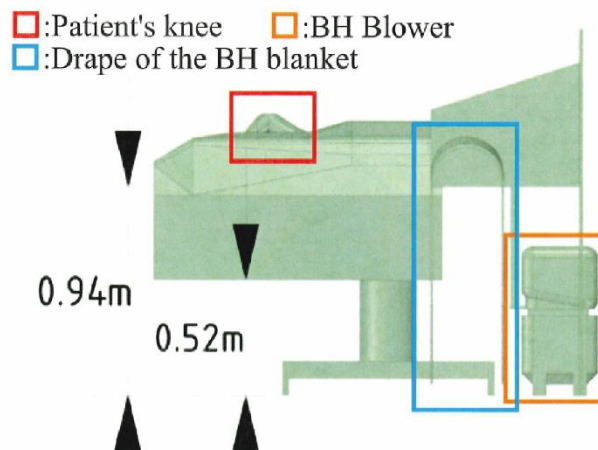
When the Bair Hugger is used for surgeries, it is my understanding, through conversations with practicing physicians and through my own work in the field, that draping is used. Furthermore, the draping is such that the warm air is not freely exhausted underneath the table, but rather is directed away from the sterile field and exits around the head and neck of the patient.

In the Elghobashi report, the air is described thusly *“The hot air moves along the surface of the drape that faces the patient and then it is discharged into the room along the drape edges.* (page 31, section 3.4.2 of plaintiff report)

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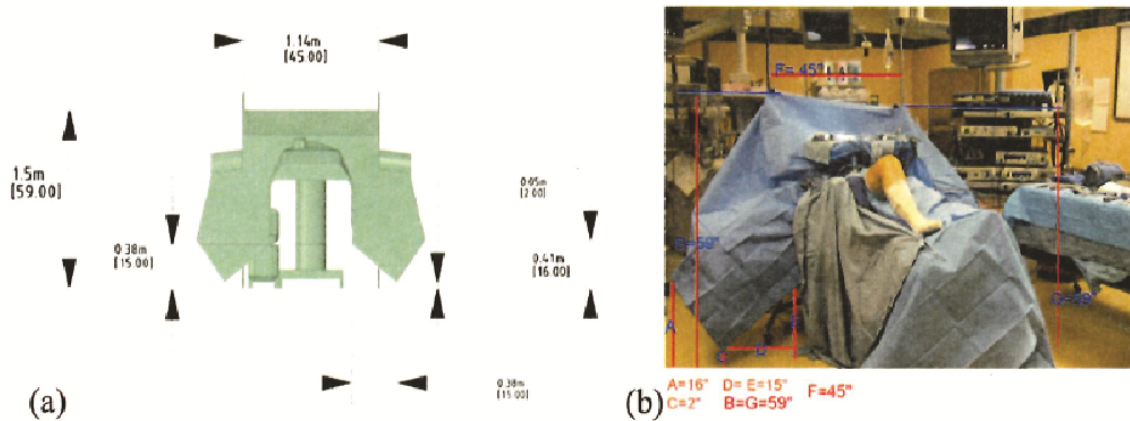
There are multiple ways to interpret this statement, and all of the possible interpretations reflect a fundamental misunderstanding.

In the computational model, it appears that Dr. Elghobashi incorporates a number of drapes. For instance, in the following image, the location of the drapes are annotated (Figure 3 of Elghobashi report). There the drapes hang nearly to the floor near the head of the surgical table.



**Figure 12 – Drapes noted from Elghobashi expert report (Figure 3). Drapes indicated by blue box.**

Later, Elghobashi describes other drapes as shown in Figure 13. This figure is reproduced from Figure 4 of his report. First, the computer image on the left of Figure 13 and the photograph on the right do not match (despite the claim by Elghobashi that the “*model [was] developed to match the drape dimensions*”). For instance, in the computerized model (left image), there is a clear line of sight underneath the table, but such an opening does not appear in the corresponding photograph.

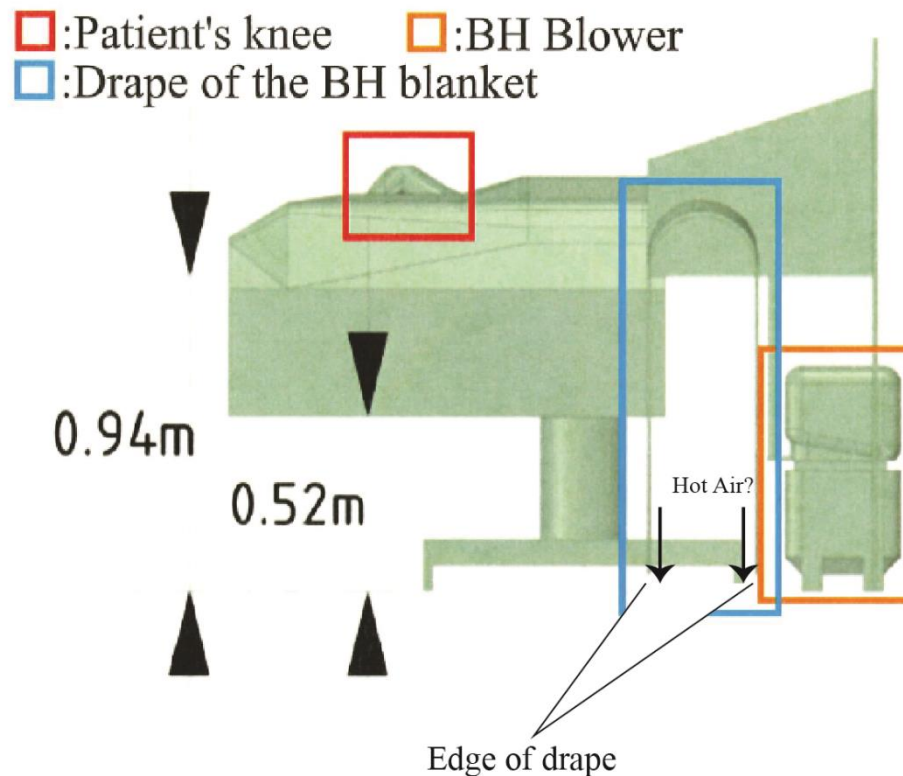


**Figure 13. This is Figure 4 from Dr. Elghobashi’s expert report. Side-by-side image which reportedly shows drape configuration and matching OR photograph. Note that they do not match.**

From this discussion, two items are apparent. First, we do not know which drapes are referred to by Elghobashi as he discusses the hot air entering the room. Second, we see that his computer model does not match reality. But regardless, even if we assume that the annotated drapes are correct, as shown in Figure 14, it appears that Elghobashi believes that air travels downwards and emerges at the “edge of the drape” as shown in Figure 14. There, the edges of the drape are labeled and two arrows show hot air traveling to the edge of the drape, as described by Elghobashi. In fact, this interpretation is supported by his statement on page 57 of his report that “*Some of the edges of the drape are very close to the floor.*” In other words, it appears that Dr. Elghobashi has assumed in his boundary conditions that air will exit *the bottom of the drape* at the same temperature and velocity at which it exits the microperforations in the Bair Hugger blanket. Moreover, he assumes that the air will exit the bottom of the drape *in a jet*, despite the fact that, as shown above, air emitted from the microperforations will quickly dissipate in a matter of inches from the blanket.

This interpretation displays a misunderstanding of air flow and basic physics. Air, as it emerges into a large space, spreads out. This is even more true for air that has extra heat. We know this from personal experience. For instance, people commonly blow on soup to cool it for consumption. While blowing air, if you put your hand near your mouth, you will feel a strong jet of air. As you move your hand away from your mouth, the jet of air will diminish. In fact, when your arm is fully extended, the jet will be much less powerful than at your mouth. From this simple example we understand air jets spread rapidly. This intuitive experiment is supported by many academic studies and theory. In contrast, Dr. Elghobashi apparently believes that the air will continue downwards along the drape to the floor and emerge as a jet there. This is demonstrably incorrect, as shown in the schlieren images above, and is a serious error that makes his entire analysis incorrect.

If my interpretation of Elghobashi’s computational model is incorrect, it is because he has insufficiently described his analysis. I reserve the right to modify this report if Dr. Elghobashi offers any clarification of this inherent flaw in his model.

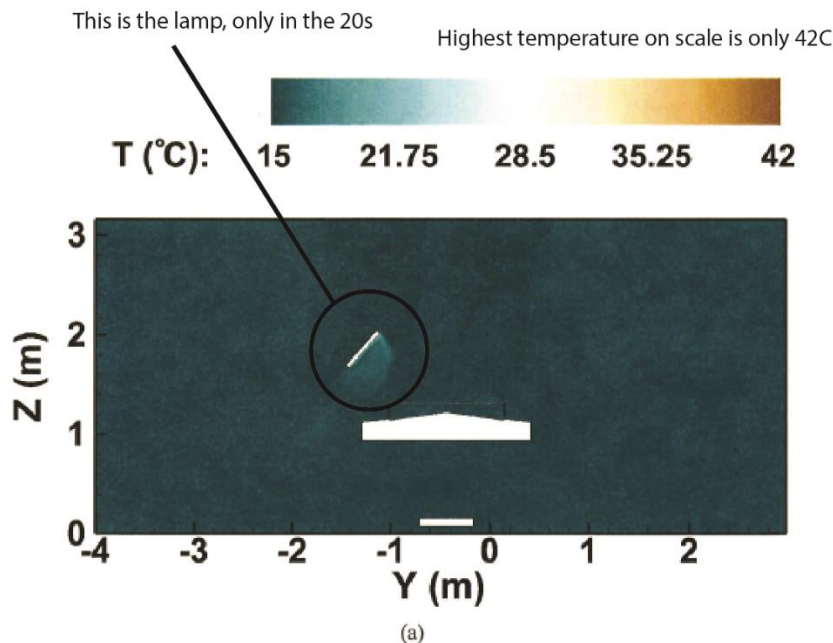


**Figure 14 – Potential interpretation of plaintiff model for hot air entering room.**

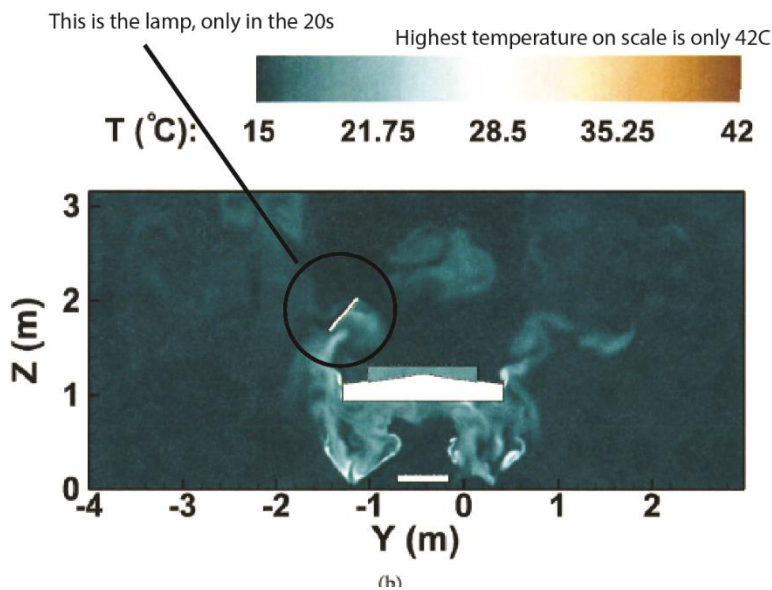
**F.3. He has removed the most significant heat source from his analysis, despite defining it as part of his model.**

Dr. Elghobashi gives much attention to the effect of heat on air flow within the room. He is correct in that hot air rises by an effect called buoyancy. In his model description, Elghobashi claims to include lamps which are at temperatures of 93.92 °C (Table 2 of his report). However, when results are shown, no temperatures of this value are seen. For instance, I show Figures 15 and 16 which are from his report. Despite claims of including hot lamps, the results show otherwise. As seen, the temperature scale at the top of the images only extends to 42C. Furthermore, the temperatures near the lamps appear to be in the 20C range (not the 93.92C claimed). This omission is another fundamental flaw in the analysis of Elghobashi.





**Figure 15 – Annotated image from plaintiff’s report showing that despite claims, the lamp is not at 93.92C and highest temperature on scale is only 42C.**



**Figure 16 – Another annotated image from plaintiff’s report showing that despite claims, the lamp is not at 93.92C and highest temperature on scale is only 42C.**

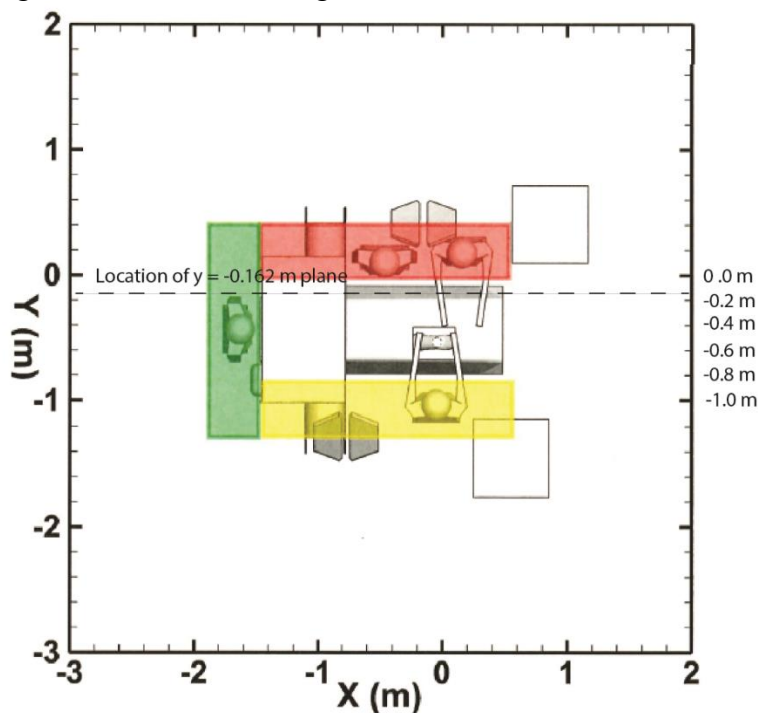
**F.4. He claims to present information along two precisely located planes that pass through the room but in fact his results do not correspond to his purported location.**

To demonstrate this clear error, Figure 17 is prepared. This figure is taken from Elghobashi’s report (Figure 21 from his report). On the right hand side, I have annotated the Y tick marks between 0 and -1 m. A dashed line is shown at the -0.162 m location. Notice that the dashed line



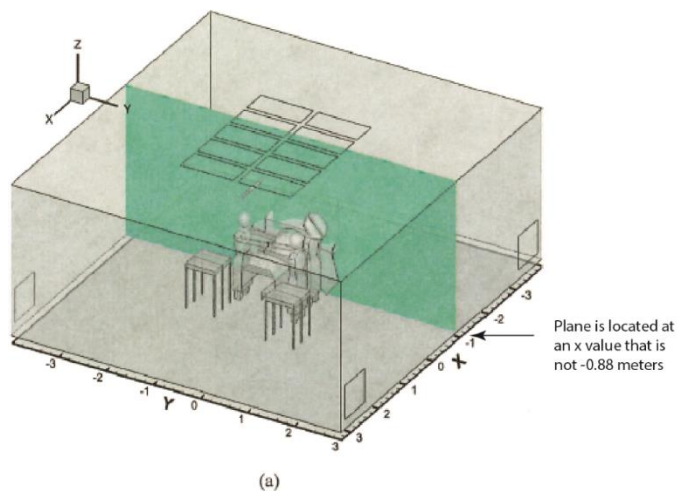
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does not pass through the bodies of the surgeons in the model.

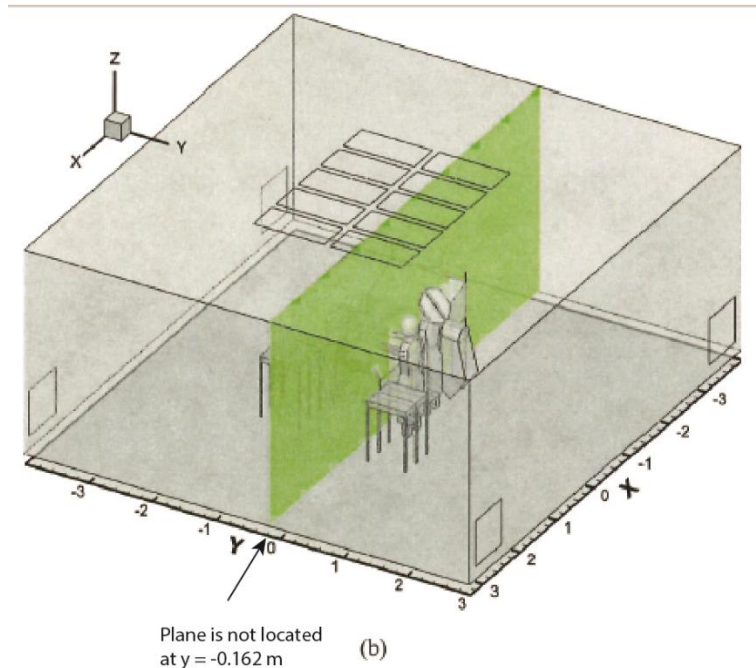


**Figure 17 – Annotated Figure 21 from Elghobashi report showing the location of plane at  $y = -0.162$  meters**

Figures 18 and 19 are also from Elghobashi's report. I have annotated them to show that these planes are not located where they are claimed to be (at  $x = -0.88$  m and  $y = -0.162$  m)



**Figure 18 – Image taken from Figure 14a of Elghobashi's report. Annotated to show that the plane is not located where claimed.**



**Figure 19 – Image taken from Figure 14b of plaintiff’s expert report. Annotated to show that the plane is not located where claimed.**

Throughout the Elghobashi report, it is repeatedly stated that results are shown for two precisely located planes. The two planes are claimed to be located at  $x = -0.88$  m and at  $y = -0.162$  m.

This error is made more clear when one considers his results. For instance, Figure 20 is shown below which is also Figure 20 from the Elghobashi report. In the reproduction, I have included the caption which clearly states that the contours are taken from the  $y = -0.162$  m plane. In the image, the plane is shown to be passing through two of the simulated surgeons (they appear white). But, as seen above in Figure 17, the plane in question does not pass through the surgeons. Therefore, there is an inconsistency in the report. Dr. Elghobashi claims to show results on planes with precise locations but in fact, he shows results elsewhere at an unknown location.

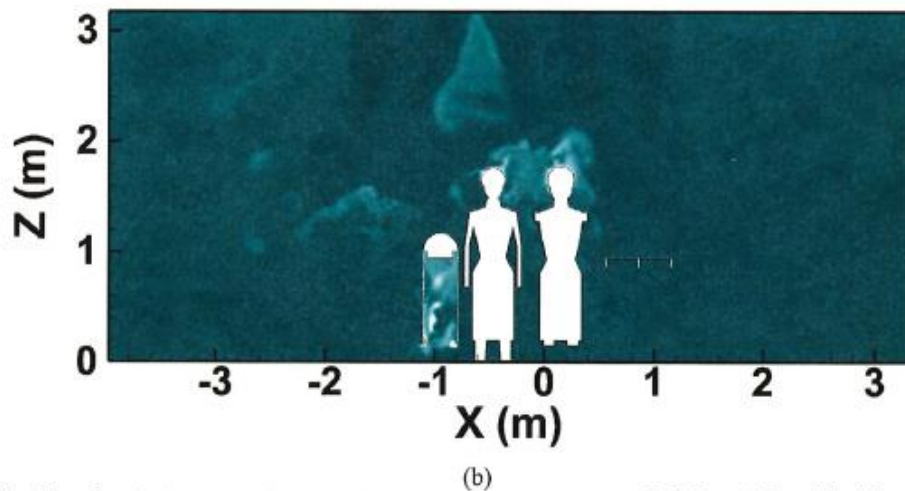


Figure 20: The instantaneous temperature contours at  $y = -0.162\text{m}$  (a) with blower-off and (b) with blower-on. These snapshots are at about 35s after a stationary flow field was obtained and

**F.5. His treatment of skin cells as spheres not only has a mathematical error but is based on a faulty premise.**

Dr. Elghobashi makes two errors in his treatment of skin cells/squames as spherical.

$$F_d = C_{d,\text{disc}} \frac{1}{2} \rho_g U_{\text{disc}}^2 A_p, \quad \text{This means the "disk" is oriented perpendicular to the direction of motion} \quad (25)$$

$$F_g = (A_p h_{\text{disc}}) \rho_p g; \quad A_p = \frac{\pi}{4} D_{p,\text{disc}}^2 \quad (26)$$

$$C_{d,\text{sphere}} = \frac{24}{Re} \quad (30)$$

$$C_{d,\text{disc}} = \frac{20.4}{Re}, \quad \text{flow normal to circular disc} \quad (31)$$

$$= \frac{13.6}{Re}, \quad \text{flow parallel to circular disc.} \quad (32)$$

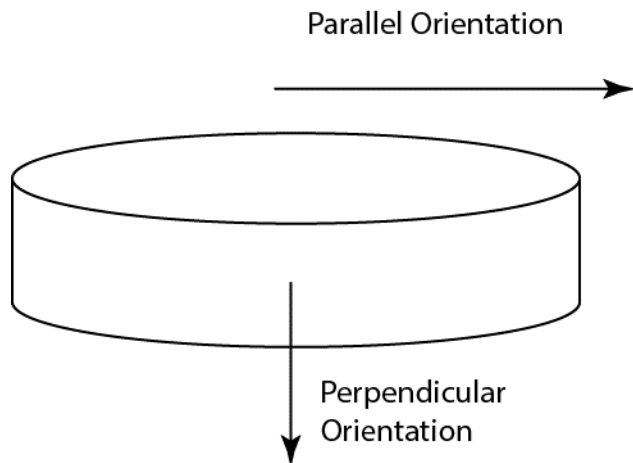
Inconsistent assumptions

This means the "disk" is oriented parallel to the direction of motion

**Figure 21 – Annotated screenshots from Appendix A of Elghobashi report.**

To explain in more detail, in Appendix A of the plaintiff's expert report, the two motion

directions shown in Figure 22 are conflated with each other. It is well known that the aerodynamics and motion of a disk in these two directions are very different. Consider for instance a frisbee (which is a disk). A frisbee would move much differently depending on whether it was thrown with a parallel or a perpendicular orientation (regardless of whether the Frisbee is spinning).



**Figure 22 – Two very different directions of motion which are interchanged in Elghobashi report.**

With this understood, it is clear that Elghobashi has made a serious error in Appendix A. However, even if this error were corrected, there would still be a serious error. That is, you cannot treat a disk-like object as if it were a sphere. Disks and spheres have very different aerodynamics (a frisbee does not move like a ball). His discussion of comparing settling velocities has no relevance to the situation, rather the aerodynamic differences of the particles must not be ignored.

Another error is that the Elghobashi report mentions lift forces on squames/cells. However, spheres cannot have lift forces (unless they are spinning in air). So, the use of a sphere surrogate is at odds with his claim to incorporate lift forces. Here again, Dr. Elghobashi appears to contradict himself.

#### **F.6. His treatment of collisions as perfectly elastic is demonstrably false.**

Yet another flaw in Elghobashi's analysis is his treatment of collisions, which involves another self-contradiction. On page 23, he writes, "*In addition, if the squames impact internal boundaries, a simple, perfectly elastic specular reflection is assumed...*" (lines 429-430). This means the collisions are treated as if the squames are akin to rubber balls that bounce off walls with the exact same energy they had before collision. For perfectly elastic collisions, the squames cannot adhere to any surface. So, this assumption exactly contradicts the statement made a few lines later (lines 432-433) where it is stated "*they are assumed to stick to the surface and are no longer advanced in the computations.*"

What is evident is that within a few lines, Dr. Elghobashi takes two contradictory positions.

Furthermore, the assumption of a perfectly elastic collision is false. When squames or other particles collide with a surface, there is a likelihood that they will adhere. This is why dust settles on surfaces – dust which is first airborne then collides with a surface and adheres. If airborne particles truly had elastic collisions, dust would never settle on surfaces. In reality, squames which are airborne in a room will settle on surfaces. They will not “bounce off” and continue on their pathway. But Dr. Elghobashi has assumed that skin squames will never settle until they reach a surgical site. Given this deeply flawed assumption, his results are not credible.

**F.7. His inlet vent conditions have two serious errors related to the incorrect duct assumptions and to the neglect of exit vanes.**

The error to be discussed here is associated with the ceiling vents. To aid in the discussion, Figure 23 is provided. In this figure, and in the accompanying discussion, Elghobashi explains how the air enters the room at the ceiling. It is described as fully developed and turbulent. At lines 492-493 he states *“it is necessary to impose a proper fully developed turbulent flow field at the inlet...”*

For background, a “fully developed flow” is a flow that occurs when it passes through a long tube or duct that is straight. In fact, the right hand side of Figure 23 shows the concept. The duct is envisioned to be periodic, straight, and vertical. Physically, this means that duct is infinitely long, straight, and vertical. Such ducts do not exist in hospitals. Ducts carry air from a furnace or AC system to an operating room by passing horizontally (typically between floors) and vertically (from one floor to another). They are not purely vertical and they are not infinitely long. As a consequence, his assumption of a “fully developed” flow in the duct is demonstrably false.

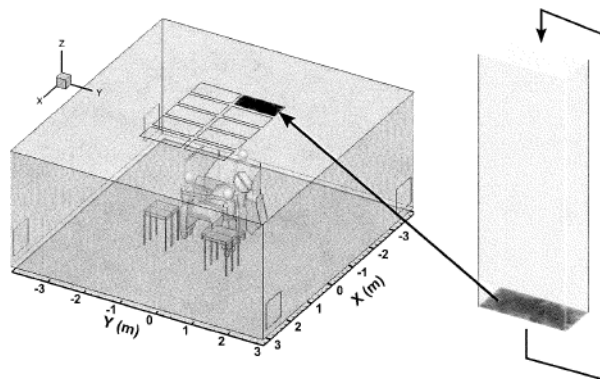


Figure 12: Schematic of the periodic duct used to generate inlet flow data.

**Figure 23 – This image is taken from Figure 12 of the Elghobashi report.**

A second and independent error is that Dr. Elghobashi ignored the grille which exists at the ceiling vents. The presence of the grill will completely invalidate his assumed velocity profile (shown in his Figure 13). To provide some perspective, Figure 24 is prepared which is taken from the Elghobashi report. I have included the caption used in the Elghobashi report which is

“Mean velocity profile generated by a periodic duct flow for the inlet grills.” However, the velocity shown in this figure is not what emerges from the inlet grills, in fact, there is no evidence that the inlet grill was even included in his analysis. As the airflow passes through the ceiling grill, small eddies and turbulence are created and the velocity profile becomes flatter than that of Figure 13. So, the caption used by Elghobashi in his Figure 13 (my Figure 24) contradicts his assumption of fully-developed periodic flow in a duct.

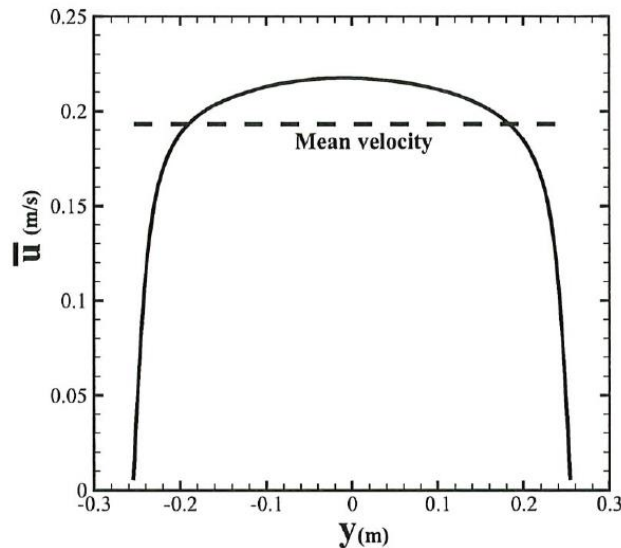


Figure 13: Mean velocity profile generated by a periodic duct flow for the inlet grilles.

**Figure 24 – This image is taken from Figure 12 of the Elghobashi report.**

### **F.8. Summary evaluation of plaintiff’s expert report**

As discussed in this section, the plaintiff’s expert makes several flawed assumptions and basic errors which render his conclusions invalid. Furthermore, his methodology is not accepted by persons in the field of fluid mechanics as they use unvalidated numerical simulation to match real-world results.

## **G. ONLINE VIDEOS ARE MISLEADING**

A website ([heat-rises.blogspot.com](http://heat-rises.blogspot.com)) contains three videos which reportedly support the plaintiffs’ claim that heat from the Bair Hugger can cause particles to enter the surgical field. These videos are faulty at best, and misleading and dishonest in my opinion.

The videos are entitled:

1. Forced Air Patient Warming Causes Vortex That Deposits Contaminants Within Surgical Field
2. Airborne Contamination in the Operating Room
3. Forced-Air Warming Destroys Laminar Air-Flow

Among the central claims from these videos is that waste heat from forced-air blowers causes



rising currents that penetrate the laminar zone. This is a demonstrably false claim. The Principal Investigator, Robert Gauthier, reports that the Bair Hugger generates 900 Watts of waste heat. There is no experiment or analysis I am aware of which support this claim. First, my own experiments and basic conversation of energy principles prove that the amount of heat generated by these systems is far less than 900 Watts. Furthermore, Dr. Gauthier completely neglects heat taken up by the human body and heat taken up and released by other objects in the room. Finally, and perhaps more importantly, Dr. Gauthier's team express a false notion of fluid flow. While it is true that warm air tends to rise, such motion must be considered in the context of the surroundings; for instance, the surrounding temperatures and airflow. In a laminar room or a standard operating room with downward cool airflow, the downward air flow is many times larger than that of the airflow from the Bair Hugger. As a result, the downward airflow dominates over any other currents in the room, pushing the Bair Hugger airflow toward the sides of the room and out the vents. The mass of the downward airflow is enormous compared to the Bair Hugger air. An analogy is the mass of a train compared to the mass of a small car. In a collision, the car will be pushed by the train, not the reverse. This same effect is seen in both experiments and in the calculations. In an operating room, even if bacteria were carried by a downward moving air stream, the air would not then turn around and rise against the downward ventilation flow.

These videos are self-contradictory. For instance in some cases a claim is made that the screen causes a dead zone above the patient whereas in other cases, it is claimed that a dead zone is caused by lighting. Regardless, these flow visualization movies appear to be intentionally misleading with different draping, distances from injection port to drape, different drape contour, and different lighting. It also appears that different flow was used. Regardless, no information was given about flow rate, bubble concentration, or other critical details needed to replicate this work. A fair comparison would be to video a situation with and without a properly draped patient in an operating room with a surgical team, and without halt to the video itself.

Little information was given about the surgical room, the venting flowrate and temperature, or the flow and temperature of the warming blanket. Statements about the amount of heat generated by the Bair Hugger are simply false. No measurements were provided and the description of measurements does not allow reproduction of the results. This lab setup appears designed to give poor airflow results.

The laser lighting video contradicts assertions about laminar flow being delicate and able to be easily disrupted. In addition, the laser videos involved moving light sources in a misleading manner to give inferences of differences in performance. Again, the paucity in the description makes it impossible for other researchers to reproduce the results.

The opposition has made multiple claims about how forced-air warmers may lead to infections. They have provided multiple contradictory explanations for how this may occur. It may be due to a dead zone created by a drape, a dead zone created by lights, buoyant air rising from the patient, warm air that leaves the blanket, travels to the floor where it picks up bacteria which are then carried to the surgical site, contaminated air that is created within the device, air from the floor which is sucked through the device and then exhausted onto the surgical site, air from the device which picks up contaminated skin cells and then deposits them at the surgical site, and other



explanations. These are sometimes mutually exclusive and there is no reliable evidence which supports any of these explanations. None of these videos are supported by any experimental research which can be reproduced, which was submitted to a heat transfer, fluid flow, engineering journal, which is realistic, or which actually shows increased infection due to these blankets. These unsupported hypotheses have all been shown faulty by experiments, by my own calculations and by basic physics.

I am an expert in buoyant flow, in laminar flow, in turbulent flow, in forced-air warmers, with airflow experiments, with airflow calculations, and in tracking flow patterns. I have seen no evidence that would indicate forced-air warming can bring pathogens to a surgical site.

## **H. CONCLUDING REMARKS**

My opinion is that forced-air patient warming does not disrupt airflow in a way that would present a significant risk of infection.

My opinion is supported by multiple independent lines of evidence. The lines of evidence are my own calculations, experiments in an operating room environment, and my assessment of the scientific literature. These strongly confirm that there is no evidence forced-air warming systems increase the chances of infection. There is no evidence that pathogens are transferred from the inside of the device, from the flow, from the patient, or other parts of the room to the surgical area.

In terms of upsetting the room air motion, focus should be given to movement of people or equipment, or opening of doors and other motion. These motions have the potential to cause much more significant flow alteration than the Bair Hugger.

The evidence which purports to contradict my assessment is lacking in quality and/or is incomplete.



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